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Pest Management Regulatory Agency

Santé Canada
Agence de réglementation de la lutte antiparasitaire

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PROPOSED RE-EVALUATION DECISION

Re-evaluation of S-ethyl Dipropylthiocarbamate (EPTC)

(publié aussi en français)

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EXECUTIVE SUMMARY

Health Canada's Pest Management Regulatory Agency (PMRA) has re-evaluated the available information on the active ingredient EPTC and the associated end-uses on food and non-food areas. The PMRA is proposing that the use of EPTC and its end-use products is acceptable for continued registration with the implementation of additional mitigation measures to further protect workers, residents and the environment.

The following summarizes the health and environmental risk assessments as well as the proposed mitigation measures resulting from the re-evaluation of EPTC.

Human Health Risk Assessment

For domestic class products, the calculated margins of exposure for postapplication inhalation exposure were below the target margin of exposure; therefore, it is proposed that domestic class products be phased out unless data are provided to mitigate this concern. Application and postapplication risks to workers are acceptable, except for use in combination with dry fertilizers for which the calculated margins of exposure are less than the target margins of exposure. Exposure to residues of EPTC in drinking water and food is below the level of concern. When residential use is excluded, aggregated exposure to EPTC through food, water and air was below the level of concern.

Environmental Risk Assessment

The environmental risk assessment indicates that EPTC poses a negligible risk of adverse effects to pollinators, birds, small mammals, freshwater invertebrates and fish, and marine/estuarine invertebrates. There is a moderate risk to non-target terrestrial plants, aquatic vascular plants and algae from drift of EPTC into non-target areas. The risk to non-target organisms from spray drift can be mitigated by observing buffer zones.

Proposed Mitigation Measures

- Domestic class products as well as use for fertilizer impregnation (on-farm and commercial) will be phased out unless adequate data are provided.
- Additional personal protective equipment is required for mixers, loaders and applicators using granular and emulsifiable concentrate formulations.
- A restricted-entry interval of 24 hours is required before people/workers may enter treated areas.
- Additional precautionary measures to prevent runoff, leaching and volatization are required.

- Directions for use must clearly indicate no more than two applications are allowed per year for commercial class products.

- Terrestrial and aquatic buffer zones are required for application of emulsifiable concentrate formulations.

Next Steps

By way of this document, the PMRA is soliciting comments from interested parties on the proposed regulatory decision for EPTC. The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document to allow interested parties an opportunity to provide input into the proposed decision. All comments should be forwarded to Publications (contact information on the cover page of this document).

SCIENCE EVALUATION

1.0 Introduction

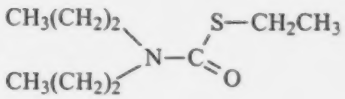
Health Canada's Pest Management Regulatory Agency (PMRA) announced in August 2002 that selected carbamate active ingredients, including EPTC, were subject to re-evaluation. This document includes a human health assessment and environmental assessment of EPTC.

2.0 Re-evaluation of EPTC

EPTC is a thiocarbamate herbicide (resistance management group 8) that inhibits lipid synthesis (not acetyl CoA carboxylase inhibition). It works by systemic action. EPTC is registered for the control of a variety of annual grasses, broadleaf weeds and selected perennial weeds in terrestrial feed, food and oilseed crops and as a domestic class product for use in ornamentals in a residential setting.

The PMRA based its assessment of EPTC on information and data from the registrant and United States Environmental Protection Agency (USEPA) reviews and reports, including the 1999 Reregistration Eligibility Decision for EPTC.

2.1 Identity of the Active Substance

Active Substance	EPTC
Chemical Names	
International Union of Pure and Applied Chemistry (IUPAC)	*S*-ethyl dipropylthiocarbamate
Chemical Abstracts Service (CAS)	*S*-ethyl dipropylcarbamothioate
Chemical Class	Thiocarbamate
CAS Number	759-94-4
Molecular Formula	$C_9H_{19}NOS$
Molecular Weight	189.3
Structural Formula	

Identity of Relevant Impurities of Toxicological, Environmental and/or Other Significance
This product contains a maximum of 0.7 ppm *N*-nitrosodipropylamine. It is unlikely that trace levels of nitrosamine would pose a health risk to humans. No other impurities of toxicological concern as identified in Regulatory Directive DIR98-04, Section 2.13.4, or any Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive DIR99-03, Appendix II, are expected to be present in this product.

2.2 Physiochemical Properties of the Active Substance

Property	Result*
Vapour pressure at 25°C	10×10^3 mPa
Henry's law constant	1.3×10^{-2} Pa m^3 mol^{-1}
Ultraviolet (UV)–visible spectrum	Not expected to absorb UV at $\lambda > 350$ nm
Solubility in water at 25°C	375 mg/L
n-Octanol–water partition coefficient at 25°C	log K_{ow} = 3.2
Dissociation constant	None

* Data from *The e-Pesticide Manual*, 12th edition, V.2.2, British Crop Protection Council

2.3 Description of Registered EPTC Uses

Appendix I lists all EPTC products that are registered in Canada, and Appendix II lists the product's registered uses. These uses are all supported by the registrant and were considered in the health and environmental risk assessments of EPTC.

Products containing EPTC are registered under the following use-site categories: Industrial Oilseed Crops and Fibre Crops, Terrestrial Feed Crops, Terrestrial Food Crops and Ornamentals Outdoor.

EPTC controls various annual grasses, annual broadleaf weeds and perennial weeds in terrestrial food and feed crops, industrial oilseed and fibre crops as well as outdoor ornamentals.

3.0 Effects Having Relevance to Human Health

3.1 Toxicology Summary

The toxicology data base for EPTC is based primarily on studies available from the registrant. EPTC undergoes rapid systemic absorption and distribution, with the majority being excreted via the urine within 24 hours. EPTC was found to be of low to slight acute toxicity following acute oral exposure to mice and rats, of low acute toxicity to rabbits following dermal exposure, of

slight acute toxicity to rats following inhalation, minimally or slightly irritating to the rabbit eye and skin, respectively, and a non-sensitizer. In short- and long-term studies, cardiomyopathy, skeletal muscle degeneration and brain neuronal cell necrosis were among the primary effects, with males appearing more sensitive than females in rats and dogs. Studies in the rat indicated an increase in toxicity and severity of effects with increased duration. A number of pathological effects on the nervous system were noted, including neuronal cell necrosis in the brain of rats, Wallerian degeneration of the spinal cord and peripheral nerves in dogs, frequent inhibition of acetylcholinesterase and reduced brain weight in mature offspring. No delayed neurotoxicity occurred in the hen. EPTC increased mutation frequency in activated mouse lymphoma cells, but it was not found to be carcinogenic to rats or mice. Fetal malformations were noted in rats, but only at doses causing severe maternal toxicity. There was no evidence of offspring sensitivity in developmental toxicity studies in rats or rabbits, or in a reproductive toxicity study in rats. However, a developmental neurotoxicity study indicated a dose-related decrease in absolute brain weight in young adult rat offspring that had been exposed during gestation and lactation.

Reference doses have been set based on no observed adverse effect levels (NOAELs) for the most relevant endpoints, namely neuronal cell necrosis, litter viability, cardiomyopathy and hepatocellular lipidosis. These reference doses incorporate uncertainty factors to account for extrapolating between animals and humans, and for variability within human populations. Additional safety/uncertainty factors have also been applied to take into consideration the severity of effects.

The toxicology endpoints used in the risk assessment of EPTC are summarized in Appendix III.

3.2 Occupational and Residential Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE, which incorporates safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects; however, MOEs less than the target MOE require risk mitigation.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before workers or others can safely re-enter.

To estimate the risk from short-term dermal exposure (1–30 days), an oral NOAEL of 22 mg/kg bw/day from a developmental neurotoxicity study in rats was selected, in which there was an increased incidence of total litter loss at the next dose level that produced only mild toxic effects in the dams (slight decrease in body weight). The target MOE was 300; this accounts for interspecies extrapolation (10-fold) and intraspecies variability (10-fold), and includes an additional factor (3-fold) for severity of effect (litter loss) and qualitative offspring sensitivity.

To estimate the risk from short-term inhalation exposure (1–30 days), a NOAEL of 11.3 mg/kg bw/day from a subchronic inhalation study in rats was selected, in which there was an increased incidence and severity of myocardial degeneration and hepatocellular lipidosis (fatty degeneration) at the next dose level after 3 weeks of treatment. The target MOE was 300; this

accounts for interspecies extrapolation (10-fold) and intraspecies variability (10-fold), and includes an additional factor (3-fold) for severity of effect (myocardial degeneration).

The PMRA considered information from available rat dermal absorption studies and the physical/chemical properties of EPTC in a weight-of evidence approach resulting in an estimated dermal absorption value of 8%.

3.2.1 Occupational Mixer/Loader/Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders, applicators and handlers. Based on typical use patterns, the major exposure scenarios identified were as follows.

- Mixing/loading emulsifiable concentrate
- Mixing/loading granules
- Groundboom application to flax, alfalfa, birdsfoot, trefoil, cicermilk vetch, sweet clover, bean, corn, Irish potatoes, sugar beets, sunflowers and turnips (rutabagas).
- Chemigation to Irish potatoes and sugar beets
- Application of emulsifiable concentrate to dry bulk fertilizer (impregnation), then application of treated fertilizer to fields

Handler exposure was estimated based on different levels of personal protective equipment (PPE).

- Baseline PPE: Long-sleeved shirt and long pants, chemical-resistant gloves
- Medium PPE: Coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves
- Maximum PPE: Chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves
- Engineering controls: closed mixing/loading and/or closed tractor cab for application

No acceptable chemical-specific handler exposure data were submitted for EPTC; therefore, dermal exposure was estimated for the various application methods using the Pesticide Handlers Exposure Database Version 1.1 (PHED). The PHED is a compilation of generic mixer/loader/applicator passive dosimetry data with associated software that facilitates the generation of scenario-specific exposure estimates, based on formulation type, application equipment, mix/load systems and level of PPE.

In most cases, the PHED did not contain appropriate data sets to estimate exposure to workers wearing chemical-resistant coveralls or a respirator, so exposure was estimated by incorporating a 90% clothing protection factor for coveralls and a 90% protection factor for a respirator into the unit exposure data. Data were also not available to assess exposure when mixing or loading granular formulations in a closed system. In this case, a 90% protection factor for a closed system was applied to the unit exposure value for an open system.

3.2.1.1 Inhalation Exposure

For volatile chemicals or those chemicals that have a vapour pressure greater than 13 mPa, PHED unit exposure data may not be representative of the potential exposure to mixer/loaders/applicators. Given the vapour pressure of EPTC is 10×10^3 mPa, PHED data is considered to be an underestimate of inhalation exposure, the degree to which is unknown. Therefore, the PHED was deemed to be inappropriate given the significant difference in vapour pressures.

In a soil volatility study, liquid radiolabelled EPTC was applied to sandy loam soil in a flask, at a rate equivalent to 11.2 kg a.i./ha (10 lb a.i./A). The pesticide was not incorporated into the soil. Volatilized EPTC was collected by drawing air, via a vacuum pump, through a polyethylene foam plug inserted in the side arm of the flask. Most of the applied compound had volatilized in the first 2-hour period (55.9%), with an estimated air concentration of 109 mg/m^3. This air concentration dropped to 34 and 5 mg/m^3 in the 2- to 4-hour and 4- to 6-hour periods after application, respectively. As the application rate in this study is much greater than what is registered in Canada (6.9 kg a.i./ha), the reported results were normalized to the maximum Canadian application rate: 67, 21 and 3.1 mg/m^3 for the 0- to 2-hour, 2-to 4-hour and 4- to 6-hour periods postapplication, respectively. There are a number of limitations and uncertainties with this study with respect to the applicability of laboratory data to field conditions and differences in formulation.

Although there are a number of limitations and uncertainties with this study, these are the best chemical-specific data currently available for inhalation; therefore, they were used to assess inhalation exposure for both commercial and domestic class products.

3.2.1.2 Occupational Mixer/Loader/Applicator Exposure and Risk Assessment

Farmers and custom applicators can be exposed to EPTC through mixing, loading and applying the registered products to crops during normal use. In addition, workers can be exposed during the impregnation of dry bulk fertilizer with EPTC. Farmers, custom applicators and workers are expected to have short-term exposure (< 30 days).

For the fertilizer impregnation scenarios, which may occur both on-farm and in commercial facilities, appropriate data to estimate exposure to handlers treating fertilizer are not available. Exposure from commercial impregnation scenarios was estimated using PHED data, while exposure from on-farm impregnation was estimated using the PHED and data from an on-farm seed treatment study. There is great uncertainty in using these data for the fertilizer impregnation scenarios as they are not fully representative of the scenarios. As well, PHED mix/load data do not capture exposure which may occur during other aspects of fertilizer impregnation. To assess the commercial impregnation scenario, the USEPA used a closed system seed treatment study, but the relevance of this to a closed system fertilizer treatment is unknown.

Mixer, loader and applicator exposure estimates are based on the best available data at this time. The assessment might be refined with exposure data more representative of modern spray equipment and engineering controls.

As indicated by the high initial air concentrations reported in the soil volatility study (Section 3.2.1.1), significant inhalation exposure is expected for those workers handling EPTC; therefore, a respirator will be required for all mixers, loaders and applicators.

In Appendix IV, Tables 1 and 2, the calculated dermal MOEs exceed the target MOEs for the granular formulation during mixing, loading and application, provided the following PPE is worn:

Farmers/Custom Applicators

- Long-sleeved shirt, long pants, chemical-resistant gloves

For the emulsifiable concentrate formulation, the calculated dermal MOEs exceed the target MOEs for mixing, loading and applying provided the following PPE is worn:

Farmers (i.e. those handling less than 755 kg a.i./day)

- Long-sleeved shirt, long pants, chemical-resistant gloves

Custom Applicators (i.e. those handling more than 755 kg a.i./day)

- Closed mixing/loading
- Coveralls over a long-sleeved shirt, long pants, chemical-resistant gloves

In Appendix IV, Table 3, the calculated dermal MOEs did not reach the target MOE for the impregnation scenarios, with the exception of on-farm scenarios where PHED data were used. However, as mentioned above, there is great uncertainty with the data used to estimate exposure during impregnation, especially the PHED data that do not capture exposure from all aspects of fertilizer impregnation.

All proposed regulatory actions resulting from this assessment are described in detail in Section 7.0.

3.2.2 Occupational Postapplication Exposure and Risk Assessment

Postapplication exposure to workers is expected to be minimal due to the timing of applications. With the exception of potatoes, EPTC is applied to the soil and is incorporated either prior to planting or after the crops have emerged; therefore, exposure from treated foliage is expected to be negligible as there is no foliage present during application. Exposure to EPTC during harvesting or any other late season activity is not likely to occur because EPTC is applied so early in the season.

As granules are applied directly to soil (granular formulation), dislodgeable foliar residues are anticipated to be negligible. As such, dermal exposure from foliar contact activities is also considered to be negligible for agricultural re-entry workers.

Although the liquid formulations are also applied directly to soil, there is potential that the spray or spray drift could contact foliage, so an assessment of postapplication exposure to foliage was performed. Potential exposure to re-entry workers was estimated using activity specific transfer

coefficients and default dislodgeable foliar residue (DFR) values. The transfer coefficient is a measure of the relationship between exposure and DFRs for individuals engaged in a specific activity and is calculated from data generated in field exposure studies. The registrant is a member of the Agricultural Re-entry Task Force (ARTF) so the refined ARTF transfer coefficients were used.

As DFR studies were not submitted to the PMRA, the default peak DFR level of 20% of the application rate dislodgeable on day 0 and the default dissipation rate of 10% per day were used in the assessment. This default is considered to be an overestimate of exposure because EPTC is highly volatile and residues are expected to quickly dissipate following application.

Postapplication risk is managed by establishing an REI for specific tasks. Pesticide residues dissipate and/or breakdown over time, and an REI is the length of time required for the dislodgeable pesticide residues to dissipate to such a level that entry into a treated area does not result in unacceptable exposure.

As seen in Appendix IV, Table 4, some of the MOEs for postapplication activities in potato are below the target MOE on day 0. However, due to the conservatism in the DFR values used, the high volatility of EPTC and the fact that only residues from drift will be on the foliage, all MOEs were considered to be within the range of the target MOE on day 0.

As mentioned in Section 3.2.1.1, the period during which EPTC is actively volatilizing may be longer than what was indicated in the soil volatility study; therefore, an REI of 24 hours is required for all products.

3.2.3 Residential Mixer/Loader/Applicator Exposure and Risk Assessment

Residential applicators can potentially apply the domestic class EPTC product to residential gardens and ornamentals prior to or after growth starts in the spring. Although a maximum number of applications was not stated on the label, the registrant has indicated that up to four applications may be performed in a season. Given that homeowners may be handling EPTC for limited periods of time in the spring, they have the potential for short-term exposure to EPTC.

Although the label specified "home lawn spreaders" as the application equipment, application by belly grinder and by hand were also considered in the assessment as they are as potential homeowner application methods and are not prohibited on the label.

As seen in Appendix V, Table 1, the dermal MOEs were above the target MOE for all scenarios.

Application of EPTC is expected to be relatively quick with most of the time being spent in postapplication activities such as incorporation, which must occur immediately after application. Given the use patten and the high volatility of EPTC, risk from inhalation exposure for usage of the domestic class product was assessed using data from the soil volatility study (see Section 3.2.1.1).

3.2.4 Residential Postapplication Exposure and Risk Assessment

There is potential for short-term exposure to adults and youth re-entering residential gardens and ornamentals treated with EPTC.

Given the application scenario of a dry, granular formulation applied directly to soil, dislodgeable foliar residues are anticipated to be negligible and, as such, dermal exposure from foliar contact activities are considered negligible for homeowners and youth.

As an REI is not feasible for domestic class products and there is potential for immediate entry into treated areas, inhalation exposure was assessed for adults and youth. Exposure during application and postapplication was determined based on the air concentrations measured in the soil volatility study.

As seen in Appendix V, Table 2, the inhalation MOEs for adults and youth did not reach the target MOE. As a result, domestic class products are proposed to be phased out unless exposure data are provided and acceptable risk is demonstrated.

3.3 Dietary Exposure and Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in fruits, vegetables, milk, meat, eggs and processed products, may be ingested with the daily diet. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life (infants, children, adolescents, adults and seniors). For example, assessments take into account differences in children's eating pattern, such as food preferences and greater consumption of food relative to their body weight compared with adults.

Chronic and acute dietary risk assessments were conducted using Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID™) software and United States Department of Agriculture 1994-1998 Continuing Survey of Food Intakes by Individuals data. These dietary risk assessments considered all Canadian treated foods and relevant imported food commodities. The available field trial data have been used to refine the assessment. Anticipated residue values, percentage of crop treated and processing factors are included in the DEEM-FCID residue files. The drinking water assessment was conducted using a drinking water level of comparison (DWLOC) approach.

The available residue data do not encompass the residue definition, which includes the parent compound and transformation products or conjugates containing the thiocarbamate moiety. A conservative estimate of the transformation product residues in foods were, therefore, estimated from the hydroxylated metabolites (*N*-2-hydroxy propyl EPTC, *N*-3-hydroxy propyl EPTC and 2-hydroxymethyl EPTC), using an exposure adjustment factor derived from plant metabolism studies.

3.3.1 Acute Dietary Exposure and Risk Assessment

Acute dietary risk is calculated using food consumption and food residue values. A deterministic analysis allows all possible combinations of food consumption and residue levels to be combined to estimate a distribution of the amount of EPTC residue that might be eaten in a day. An exposure value representing the high end (95th percentile) of this distribution is compared with the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the calculated intake, called the potential daily intake, from residues is less than the ARfD, the intake is not considered to be of concern.

To estimate acute dietary risk (1 day) for all populations, the lowest observed adverse effect level (LOAEL) of 200 mg/kg bw was selected. This LOAEL was based on neuronal cell necrosis in the brain of male rats in an acute neurotoxicity study. The uncertainty factor was 1000 to account for interspecies extrapolation (10-fold), intraspecies variability (10-fold), the use of a LOAEL (3-fold) and severity of effect (necrosis) in the absence of acetylcholinesterase measurements (3-fold). The ARfD was calculated to be 0.2 mg/kg bw (200 mg/kg bw ÷ 1000). This value is considered protective of all populations including infants and children.

Deterministic acute dietary exposure analyses were performed to estimate the exposure and risk that result from the use of EPTC on domestic and imported agricultural commodities. Residue estimates were calculated from field trials, when available, reassessed American tolerances or Canadian maximum residue limits (MRLs). Specific processing factors were used for sugar beet molasses and potato granules, while empirical processing factors were used for all other commodities. The analysis for EPTC for all Canadian population subgroups at the 95th percentile is less than the reference dose and is, therefore, below the PMRA's level of concern. Risk estimates range from less than 7% of the ARfD for the general population to 15% of the ARfD for the most affected subpopulation—children 1- to 2-years old.

3.3.2 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk is calculated by using the average consumption of different foods, and average residue values on those foods, over a 70-year lifetime. This expected intake of residues is compared with the acceptable daily intake (ADI), which is the dose that an individual could be exposed to over a lifetime and expect no adverse health effects. When the expected intake from residues is less than the ADI, the expected intake is not considered to be of concern.

To estimate the risk from chronic dietary exposure, the NOAEL of 2.5 mg/kg bw/day from a two-generation rat reproduction study was selected based on increased cardiomyopathy at the next highest dose of 10 mg/kg bw/day. An overall uncertainty factor of 300 is calculated to account for interspecies extrapolation (10-fold), intraspecies variability (10-fold) and severity of effects (cardiomyopathy) (3-fold). The ADI was calculated to be 0.008 mg/kg bw/day (2.5 mg/kg bw ÷ 300). This value was considered protective of all populations.

Deterministic chronic dietary exposure analyses were performed to estimate the exposure and risk that result from the use of EPTC on domestic and imported agricultural commodities. The

same types of residue estimates and specific processing factors used in the acute dietary exposure and risk assessment were used in the chronic assessment. As well, weighted Canadian crop treated data were used as refinement criteria. The analysis for EPTC for all Canadian population subgroups is less than the reference dose and is, therefore, below the PMRA's level of concern. Risk estimates range from 3% of the ADI for the general population to 8% of the ADI for the most affected subpopulation—children 3- to 5-years old.

3.4 Drinking Water Exposure

The acute and chronic aggregate risk from food and drinking water exposure was addressed by calculating DWLOCs. DWLOCs are based on the difference between the appropriate reference dose and the estimated dietary exposure level (i.e. the portion of the reference dose that is not taken up by dietary residue component) and can be directly compared to estimated concentrations in drinking water.

The acute DWLOC values ranged from 1760 µg/L for infants, the most affected subpopulation, to 6500 µg/L for the general population. The chronic DWLOC values ranged from 74 µg/L for infants, the most affected subpopulation, to 270 µg/L for the general population. Estimated environmental concentrations (EECs) were determined from both model estimates and from the available surveillance information for EPTC. As the highest EECs did not exceed the relevant DWLOCs, risks from diet and drinking water are not of concern. The EEC values are presented in Section 4.0.

3.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation). As the exposure estimate for the residential uses of EPTC exceeds the level of concern and are proposed for discontinuation, an aggregate assessment of this use was not conducted.

The chronic and acute aggregate assessments of the drinking water and dietary exposure demonstrated that there are no health concerns for any population subgroup in Canada, including infants, children, teenagers, adults and seniors. In addition, no dietary health concerns were evident for nursing or pregnant females, or based on gender in general.

4.0 Environmental Assessment

In characterizing the environmental risk of EPTC, the PMRA used a deterministic approach that characterizes the risk by a quotient method. In this method, a risk quotient (RQ) is calculated as the ratio of the EEC to the toxicity endpoint of concern, usually a no observed effect concentration (NOEC) for the most sensitive test species. Where an NOEC is not available for a test organism, one-tenth of a lethal concentration 50% (LC_{50}) is used. RQs less than one are considered as a low risk to non-target organisms, whereas RQs greater than one indicates some degree of risk. Where possible, the risk assessments were refined using less conservative

assumptions when a risk was identified during the preliminary screening level assessment in which exposure is assumed to be 100% of the application rate.

In this assessment, EECs for aquatic and terrestrial ecosystems were based on label rates varying from 2200 to 6800 g a.i./ha. To assess the risk to aquatic organisms from runoff, concentrations of EPTC in runoff were predicted using the Pesticide Root Zone Model and Exposure Analysis Modeling System (PRZM-EXAMS). Toxicity endpoints (acute or chronic) were chosen for the most sensitive species and used as surrogates for the range of species that could be exposed following treatment with EPTC.

4.1 Environmental Fate

EPTC is very soluble in water (375 mg/L at 25°C) and has a high vapour pressure (10×10^3 mPa), which indicates that it is highly volatile. The Henry's law constant, 1.7×10^{-5} atm·m^3/mol, indicates potential volatility from moist soil and water surface. The *n*-octanol–water partition coefficient, log K_{ow} of 3.2, indicates potential for bioaccumulation.

EPTC is stable to hydrolysis at environmentally relevant pH (i.e. pH 5 to 7). It is also stable to phototransformation on soil and in water. In the air, the vapour phase of EPTC transforms rapidly (half-life estimated to be 14 hours) by reacting with photochemically produced hydroxyl radicals. EPTC, therefore, is not persistent in air. Based on laboratory studies, biotransformation half-lives of EPTC in soil ranged from 10 to 37 days and from 31 to 127 days under aerobic and anaerobic conditions, respectively, indicating that EPTC is non-persistent to moderately persistent in soil. Field dissipation studies indicate that EPTC dissipation time 50% (DT_{50}) in soil ranged from 2 to 18.8 days. It should be noted that volatilization contributed more to the initial decline than aerobic soil biotransformation.

A laboratory study on volatility of EPTC from sandy loam soil indicated that 77% of the applied EPTC volatilized within four hours. Removal of EPTC from the atmosphere occurs through indirect phototransformation and also by physical removal through wet deposition as evidenced by detection in some rain samples in the United States. The soil adsorption coefficients, *K*oc = 136–266, indicate that EPTC has a low affinity to soils. Under field conditions EPTC is expected to be of moderate to high mobility in soil. EPTC has a groundwater ubiquity score of 2.9, which classifies EPTC as a leacher.

4.2 Environmental Toxicology

EPTC is relatively non-toxic to honeybees (lethal dose 50% [LD_{50}] 11.0 µg a.i./bee) and birds on an acute (LD_{50} >2500 mg a.i./kg, bobwhite quail) and dietary (LC_{50} >2000 mg a.i./kg, bobwhite quail) basis. It is slightly to moderately toxic to mammals (LD_{50} 916–2000 mg a.i./kg) on an acute basis and highly to very highly toxic (NOEC 2.5–50 mg a.i./kg, for reproduction) on a chronic basis. EPTC is toxic to terrestrial non-target plants based on seedling emergence (effect concentration 25% [EC_{25}] 0.11 kg a.i./ha) and vegetative vigour (EC_{25} 0.24 kg a.i./ha).

EPTC is slightly toxic to freshwater invertebrates (LC_{50} 14 mg a.i./L) and fish (LC_{50} 14–27 mg a.i./L). It is also slightly toxic (LC_{50} >20 mg a.i./L) to marine invertebrates. EPTC is toxic to algae (LC_{50} 1.36 mg a.i./L) and to aquatic vascular plants (LC_{50} 5.6 mg a.i./L).

Chronic toxicity data for birds and fish were not available.

4.3 Drinking Water Concentrations

Residues of EPTC in drinking water sources in Canada were estimated using the Leaching Estimation and Chemistry Model (LEACHM) and the PRZM/EXAMS models. LEACHM was used to estimate residues in groundwater, and PRZM/EXAMS was used to estimate residues resulting from surface runoff with two receiving-water scenarios, a reservoir and a dugout. For residues in groundwater, the concentration was estimated to be 2.9 and 2.8 µg a.i./L for acute and chronic exposure, respectively. For residues resulting from surface runoff using the reservoir scenario, the acute and chronic exposure concentrations were estimated to be 46.9 and 6.8 µg a.i./L, respectively. For residues resulting from surface water runoff using the dugout scenario, the acute and chronic exposure concentrations were estimated to be 45.4 and 19.2 µg a.i./L, respectively.

Both the Canadian and American monitoring data on EPTC was considered in this assessment. Data from Canadian water monitoring studies in which EPTC was quantified and obtained from Quebec. For surface water, the lower bound acute and chronic exposure values of 2.085 and 0.06 µg/L, respectively, were estimated from the available monitoring data. EPTC was not detected in groundwater in Canada because levels were below the limit of detection of the analytical method used at the time. EPTC was detected in groundwater in the United States at a detection frequency of 4.9%, with a maximum detection value of 0.013 µg/L. Given the large amount of uncertainty surrounding the monitoring data, EPTC exposure is likely to be higher in some areas than indicated by the monitoring data; thus, the maximum acute exposure values recommended for the aggregate exposure risk assessment are the concentrations predicted by PRZM-EXAMS.

4.4 Terrestrial Assessment

The results of a screening assessment identified various levels of risk to non-target terrestrial organisms exposed to EPTC. The screening assessment indicated that EPTC would pose a low risk to earthworms (RQ 0.1) and moderate risk to bees (RQ 5). Any risk to bees is minimized because the use pattern (5–15 cm soil incorporation) will result in reduced exposure and, therefore, limit the potential risk to bees.

Based on the acute oral toxicity of EPTC to birds (NOEC 250 mg a.i./kg) and using standard PMRA exposure scenarios, it was determined that birds would have to consume contaminated food sources for 2.5–7.7 days to reach NOEC for acute effects. As the number of feeding days required for adverse effect is greater than one, there is no acute risk to birds consuming contaminated food sources. The use pattern (5–15 cm soil incorporation) and volatilization of EPTC will result in reduced dietary exposure for birds. The available data (NOEC 200 mg a.i./kg diet) indicate that EPTC would pose moderate dietary risk (RQ 1.9–5.95) to birds if the product

is applied by surface broadcast treatment. With regard to the granular formulation, assuming that 15% of applied granules are available (remain on the surface), the assessment indicated that little or no acute risk to birds is expected from dietary exposure to granules. While there was no chronic toxicity data for birds, no chronic risk is expected due to the reduced exposure potential resulting from soil incorporation.

Based on the acute oral toxicity of EPTC to small mammals (NOEC 91.6 mg a.i./kg) and using standard PMRA exposure scenarios, it was determined that animals would have to consume contaminated food sources for 0.3–0.9 days to reach the NOEC. As the number of feeding days required for adverse effects is less than one there is a potential acute risk to small mammals consuming contaminated food. The use pattern (5–15 cm soil incorporation) and volatilization of EPTC will result in reduced exposure of small mammals; therefore, the potential risk from the liquid formulation is expected to be much lower than predicted for surface broadcast applications. With regard to the granular formulation, assuming that 15% of applied rate is available (remains on the surface), the assessment indicated that there is a low risk to small mammals. Similar to birds, no chronic risk is expected due to the reduced long-term exposure potential resulting from soil incorporation.

The comparison of the EECs and the toxicity endpoint of seedling emergence (EC_{25} 0.24 kg a.i./ha; wild oats) indicates that EPTC will pose a potential risk (RQ 9–28) to terrestrial non-target plants.

The screening level risk assessment indicated that the threshold of effects for terrestrial plants are potentially exceeded. This screening assessment triggered the calculation of buffer zones to protect non-target organisms from spray drift entering the terrestrial environment. To provide protection across a range of species sensitivities, the buffer zones were determined based on an available sensitive terrestrial endpoint for non-target plants (EC_{25} for vegetative vigour).

The potential for effects resulting from drift were examined by determining the percentage of the application rate that is required to reach the threshold of effects for non-target plants. Upon considering of the most sensitive species, the percentage of drift from a single application that would result in EECs that exceed the threshold of effects would be 3.6% of the application rate. Buffer zones are required as a mitigative measure to protect non-target plants. The protection of non-target plants will require buffer zones as a mitigation measure. The calculated buffer zones to protect terrestrial organisms are presented in Section 7.2.3.

4.5 Aquatic Assessment

The results of a screening assessment identified various levels of risk to non-target aquatic organisms exposed to EPTC.

The screening level risk assessment indicated that the threshold of acute and chronic effects for aquatic organisms would be exceeded. This screening assessment triggered the assessment of the need for buffer zones to protect aquatic organisms from spray drift entering the aquatic environment and the determination of concentrations in near field aquatic systems resulting from runoff.

The potential for effects resulting from drift were examined by determining the percentage of the application rate required to reach the threshold of effects for freshwater organisms. Upon consideration of the available aquatic toxicity data, the percentage of drift from a single application that would result in EECs that exceeds the threshold of effects for the most sensitive species would be 6% of the application rate. Thus, to protect non-target aquatic organisms, buffer zones are required and were determined based on the endpoint for effects on algae (NOEC 0.136 mg a.i./L). These buffer zones are presented in Section 7.2.3.

Estimates of environmental concentrations of EPTC resulting from runoff to near field aquatic habitats runoff for specific crop related scenarios were predicted by the linked models PRZM/EXAMS. The 90th percentile (1 in 10 year) 96-hour yearly peak from the location that predicted the highest EECs was used in the acute risk assessment. In the chronic assessment, the 90th percentile (1 in 10 year) 21-day yearly peak from the location that predicted the highest EECs was used in the chronic risk assessment for aquatic invertebrates. Using the most sensitive endpoint for each species group (i.e. freshwater invertebrates, freshwater fish, estuarine/marine invertebrates), it was determined that freshwater invertebrates and fish and marine/estuarine invertebrates are at low risk (RQ 0.4–0.5) of acute adverse effects from 1 in 10 year EECs predicted for runoff. The calculated RQ for vascular plants and algae exposed to the 96-hour, 1 in 10 year concentrations predicted from runoff indicate that aquatic plants and algae are at moderate risk (RQ 1.4 and 5.8, respectively) from acute exposure to EPTC.

4.6 Environmental Assessment Conclusions

For terrestrial organisms, there is little acute or chronic risk for non-target pollinators, birds and small mammals. The potential risk is largely mitigated through reductions in exposure. The reduction in potential exposure results from the use of soil incorporation concurrent with applying both the liquid and granular formulation. A moderate to high risk (RQ 9–28) was determined for terrestrial non-target plants.

For aquatic organisms, the risk assessment was based on exposure from runoff. It was determined that freshwater invertebrates and fish and marine/estuarine invertebrates are at low risk (RQ 0.4–0.5) of acute adverse effects. Aquatic vascular plants and algae exposed to EPTC in runoff were determined to be at moderate risk (RQ 1.4 and 5.8, respectively).

The risk to non-target organisms from spray drift from the liquid formulation can be mitigated by buffer zones. Mitigation of runoff exposure will be through label advisory statements.

4.7 Environmental Risk Mitigation

EPTC can enter aquatic ecosystems through spray drift. The observance of buffer zones, however, can effectively mitigate the risk to off-site non-target organisms. Based on the spray drift predictions and the most sensitive toxicity endpoint, buffer zones for waterbodies of different depths (< 1, 1–3 and > 3 m) were calculated for mitigating the entry of EPTC into aquatic habitats.

To mitigate EPTC impact on non-target terrestrial plants and the aquatic environment from spray drift, spray buffer zones must be observed.

EPTC can also enter aquatic systems through surface runoff. Currently, there is uncertainty with respect to the efficiency of methods for mitigating the transport of pesticides in surface runoff. There are, however, advisory statements with regard to precautionary measures that must be included on product labels to minimize the risk of terrestrial and aquatic contamination from surface runoff.

5.0 Use Data and Alternatives

Data regarding the use of EPTC were consulted during the health and environmental assessments. A detailed analysis of other registered pesticides that can be used in place of EPTC has not been provided because the registrants of EPTC products have not requested the discontinuation of any existing uses. The PMRA has not identified risk concerns with any of the existing uses except for Domestic Class products and use for fertilizer impregnation, which are discussed under Section 7.2.2.2.

6.0 Other Assessment Considerations

EPTC was assessed with respect to the federal government's Toxic Substances Management Policy (TSMP) and was determined not to meet the TSMP Track 1 criteria.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document*, published on 31 May 2006.

7.0 Proposed Regulatory Action

The PMRA is proposing that the use of EPTC and its end-use products (except for domestic class products) are acceptable for continued registration with the implementation of additional mitigation measures to further protect workers and the environment.

Proposed label amendments for the uses of EPTC that are acceptable for continued registration are presented in Appendix VI.

7.1 Residue Definition

Division 15 of the Food and Drug Regulations currently provides no residue definition for EPTC. The proposed residue definition is the parent compound *S*-ethyl dipropylthiocarbamate and the hydroxylated metabolites N-2-hydroxy propyl EPTC, N-3-hydroxy propyl EPTC and 2-hydroxymethyl EPTC.

7.1.1 Maximum Residue Limits of EPTC in Food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian MRLs and to remove MRLs that are no longer supported. The PMRA recognizes, however, that interested parties may want to retain an MRL in the absence of a Canadian registration to allow legal importation of treated commodities into Canada.

The PMRA requires similar chemistry and toxicology data for such import MRLs as those required to support Canadian food use registrations. In addition, the Agency requires residue data that are representative of use conditions in exporting countries, in the same manner that representative residue data are required to support domestic use of the pesticide. These requirements are necessary so that the PMRA may determine whether the requested MRLs are needed and to ensure they would not result in unacceptable health risks.

After the revocation of an MRL or where no specific MRL for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm and has been considered a general MRL for enforcement purposes. Currently, residues of EPTC in all agricultural commodities, including those approved for treatment in Canada, are regulated by subsection B.15.002(1). However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

Division 15 of the Food and Drug Regulations currently provides no residue definition for EPTC, and no MRLs are specified. The supported food uses of EPTC are alfalfa, bean (snap, succulent or dry), corn, flax, potato, sugar beet, sunflower, sweet corn and turnip.

The general MRL of 0.1 ppm will apply for enforcement purposes with respect to the residues of EPTC in food for all commodities, including registered label uses. Parties interested in supporting an import MRL for residues of EPTC on other commodities should contact the PMRA during the comment period of this document to discuss the submission of appropriate data.

7.2 Label Modifications and Proposed Regulatory Action

7.2.1 Label Modifications Related to Dietary Risk

The technical registrant supports a preharvest interval of 49 days when EPTC is applied by irrigation water to sugar beets.

7.2.2 Proposals Pertaining to Mixer/Loader/Applicator and Postapplication Exposure

7.2.2.1 Domestic Class Products

Due to target MOEs not being reached for residential postapplication inhalation exposure, it is proposed that all EPTC domestic class products be discontinued unless adequate exposure data are provided.

7.2.2.2 Commercial Class Products

Fertilizer Use
On-farm impregnation of the liquid formulation of EPTC on granular fertilizer is proposed to be removed from commercial class labels unless adequate data are provided and acceptable risk is demonstrated. As on-farm fertilizer impregnation is not commonly used, the loss of this application method is not expected to be a concern.

For fertilizer impregnation with EPTC carried out in a commercial plant scenario, inadequate data are available to assess exposure and risk. The data available to estimate exposure were not representative of this scenario and resulted in calculated MOEs less than the target MOE. Directions for this application method will need to be removed from labels unless exposure data, specific to this scenario that demonstrate acceptable risk, are provided. In addition, use of liquid EPTC would no longer be acceptable as a fertilizer-use pesticide for combinations as approved by Agriculture and Agri-Food Canada. This limitation does not apply to formulations of EPTC combined with similar forms of fertilizer (e.g., granular/granular mix).

Granular Formulation—Label Statements For Commercial Class Products
The following statements are required on the label of commercial class granular products to protect mixers, loaders and applicators:

> Wear long-sleeved shirt and long pants, chemical-resistant gloves, socks, chemical-resistant footwear and respirator during mixing, loading, application, clean up and repair. The respirator must be equipped with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister approved for pesticides.
>
> Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours.

Emulsifiable Concentrate Formulation—Label Statements for Commercial Class Products
The following statements are required on the label of commercial class granular products to protect farmers (i.e. those handling less than 755 kg a.i./day) and custom applicators (i.e. those handling more than 755 kg a.i./day):

> Wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, socks, chemical-resistant footwear and respirator during mixing, loading,

application, clean up and repair activities. The respirator must be equipped with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister approved for pesticides.

When handling more than 755 kilogram of active ingredient per day (i.e. treating over 110 ha at highest label rate of 6.8 kg a.i./ha), a closed mixing and loading system is required. Handlers must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, socks, chemical-resistant footwear during application, clean-up and repair. A respirator is also required during application. The respirator must be equipped with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister approved for pesticides.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 24 hours.

7.2.3 Proposals Pertaining to Environment

Under **ENVIRONMENTAL HAZARD,** the following must be added to the label:

TOXIC to wild mammals. **TOXIC** to aquatic organisms and terrestrial plants.

Observe buffer zones specified under **DIRECTIONS FOR USE**.

Under **DIRECTIONS FOR USE**, the following must be added to the label:

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural and Biological Engineers (ASABE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer, inter-row hooded sprayer, spot treatment, soil drench and soil incorporation.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands), sensitive freshwater habitats (such as

lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:		
		Aquatic Habitat of Depths:		Terrestrial Habitat
		Less than 1 m	Greater than 1 m	
Field sprayer*	Corn, potatoes	1	1	4
	Flax, cicer-milk, sugar beets	0	0	2

*For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

7.2.4 Proposed Regulatory Action Relating to Value

EPTC commercial class products are registered for use as pre-planting or pre-emergent with a possibility of one irrigation application; therefore, assessments were based on two applications per year. For clarification, the following statement should be added to all EPTC labels under the **DIRECTIONS FOR USE** section:

> Make no more than two applications per year.

For end-use product labels with sugar beets, under "Sugar Beets—Sprinkler irrigation water", remove any references to the tank mix with the product RO-NEET© because this product is no longer registered. Add the following statement to product labels:

> Do not apply within 49 days of harvest.

8.0 Additional Data Requirements

8.1 Data Requirements Relating to Toxicology

No additional toxicology data requirements were identified for re-evaluation of the EPTC technical product.

8.2 Data Requirements Related to the Occupational Exposure Assessment

No additional data are required for re-evaluation of EPTC. However, Should the registrant wish to maintain registration of EPTC for the on-farm and/or commercial fertilizer impregnation scenarios, the following data would be required:

- DACO 5.2 Use Description/Scenario (including extent of use)
  AND
- DACO 5.4 Mixer/Loader/Applicator—Passive Dosimetry Data
  OR
- DACO 5.5 Mixer/Loader/Applicator—Biological Monitoring Data

Should the registrant wish to remove the requirement of a respirator for mixers/loaders/applicators and/or decrease the REI for commercial class products, data to better characterize inhalation exposure would be required. Some of the following studies may address these data gaps; however, consultation with the PMRA to discuss study designs is recommended:

- DACO 5.6 Postapplication—Passive Dosimetry Data
  AND/OR
- DACO 5.7 Postapplication—Biological Monitoring Data
  AND/OR
- DACO 5.10 Ambient Air Samples

Should the registrant wish to maintain registration of the domestic class product, data to better characterize inhalation exposure would be required. Some of the following studies may address these data gaps, however, consultation with the PMRA to discuss study designs is recommended:

- DACO 5.6 Postapplication—Passive Dosimetry Data
  AND/OR
- DACO 5.7 Postapplication—Biological Monitoring Data
  AND/OR
- DACO 5.10 Ambient Air Samples

8.3 Data Requirements Relating to Food Residue Exposure

No additional data are required for re-evaluation of EPTC.

8.4 Data Requirements Relating to Environmental Risk

No additional data are required for re-evaluation of EPTC.

9.0 Proposed Re-evaluation Decision

Health Canada's PMRA is proposing that the use of EPTC and associated end-use products is acceptable for continued registration. Additional mitigation measures to further protect workers, residents and the environment have been identified.

List of Abbreviations

°C	degree(s) Celsius
µg	microgram(s)
A	acre
ADI	acceptable daily intake
absd	absorbed
a.i.	active ingredient
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
ASABE	American Society of Agricultural and Biological Engineers
atm	atmospheres
ATPD	area treated per day
BHSE	British Health and Safety Executive
bw	body weight
cm	centimetre(s)
DEEM-FCID	Dietary Exposure Evaluation Model-Food Commodity Intake Database
DER	Data Evaluation Report
DFR	dislodgeable foliar residue
DT_{50}	dissipation time to 50%
DWLOC	drinking water level of comparison
EC_{25}	effect concentration 25%
EEC	expected environmental concentration
EXAMS	Exposure Analysis Modeling System
g	gram(s)
ha	hectare(s)
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
L	litre(s)
lb	pound
LEACHM	Leaching Estimation and Chemistry Model
LOAEL	lowest observed adverse effect level
m^3	metre(s) cubed
mg	milligram(s)
M/L	mixer/loader
M/L/A	mixer/loader/applicator
mPa	millipascal(s)
MOE	margin of exposure
mol	mole
MRL	maximum residue limit
MSHA	Mininig Safety and Health Administration
NIOSH	National Institute of Occupational Safety and Health
nm	nanometre(s)
NOAEL	no observed adverse effect level

NOEC	no observed effect concentration
Pa	Pascal(s)
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRZM	Pesticide Root Zone Model
REI	restricted-entry interval
RQ	risk quotient
SF	safety factor
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UF	uncertainty factor
UV	ultraviolet

Appendix I EPTC Products Currently Registered (excluding discontinued products or products with a submission for discontinuation) as of 5 July 2005

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
7062	Commercial	Gowan Company	EPTAM 5-G Granules Selective Herbicide	Granular	5%
9921	Domestic	Gowan Company	EPTAM 2.3-G	Granular	2.3%
11284	Commercial	Gowan Company	EPTAM 8-E Emulsifiable Liquid Selective Herbicide	Emulsifiable concentrate or emulsion	800 g/L
11289	Commercial	Gowan Company	EPTAM 10-G Granular Herbicide	Granular	10%
12239	Commercial	Gowan Company	ERADICANE 8-E Selective Herbicide Emulsifiable Liquid	Emulsifiable concentrate or emulsion	800 g/L
22884	Technical	Gowan Company	EPTAM Technical	Solution	922 g/L
24060	Commercial	Gowan Company	ERADICANE 25-G Selective Herbicide	Granular	25%

Appendix II Registered Canadian Uses of EPTC as of 5 July 2005

Site(s)	Pests(s)	Marketing Class	Formulation Type	Application Methods and Equipment	Comments
Use-Site Category 13, Terrestrial Feed Crops					
Alfalfa and Birdsfoot Trefoil (new seedlings)	Annual Grasses: Annual Blue Grass, Annual Rye Grass (Italian Rye Grass), Barnyard Grass (Water Grass), Crab Grass, Foxtails (Green and Yellow), Goose Grass, Volunteer Grains (Barley, Oats and Wheat), Wild Oats, Witch Grass, Fall Panicum Annual Broadleaf Weeds: Common Chickweed, Corn Spurry, Hairy Nightshade[a], Henbit (Deadnettle), Lamb's Quarters, Pigweed (Prostrate, Redroot and Tumble), Purslane, Nettleleaf Goosefoot Perennial Weeds: Quack Grass (Couch Grass and Twitch Grass), Yellow Nutsedge	Commercial	Emulsifiable concentrate, granule	Ground sprayer, ground spreader	
Cicermilk Wetch and Sweet Clover (for seed production)		Commercial	Emulsifiable concentrate	Ground sprayer	Emulsifiable concentrate formulation can also be sprayed on granular fertilizer that is going to be applied with a ground spreader.
Use-Site Category 14, Terrestrial Food Crops					
Beans, snap or dry (including red kidney beans)	Annual Grasses: Annual Blue Grass, Annual Rye Grass (Italian Rye Grass), Barnyard Grass (Water Grass), Crab Grass, Foxtails (Green and Yellow), Goose Grass, Volunteer Grains (Barley, Oats and Wheat), Wild Oats, Witch Grass, Fall Panicum Annual Broadleaf Weeds: Common Chickweed, Corn Spurry, Hairy Nightshade[a], Henbit (Deadnettle), Lamb's Quarters, Pigweed (Prostrate, Redroot and Tumble), Purslane, Nettleleaf Goosefoot Perennial Weeds: Quack Grass (Couch Grass and Twitch Grass), Yellow Nutsedge Note: Nettleleaf Goosefoot is not registered for Sweet Corn	Commercial	Emulsifiable concentrate, granule	Ground sprayer, ground spreader	
Potatoes		Commercial	Emulsifiable concentrate, granule	Ground sprayer, ground spreader, chemigation	
Corn (sweet)		Commercial	Emulsifiable concentrate, granule	Ground sprayer, ground spreader	

Site(s)	Pests(s)	Marketing Class	Formulation Type	Application Methods and Equipment	Comments
Use-Site Category 13, Terrestrial Feed Crops; Use-Site Category 14, Terrestrial Food Crops					
Sugarbeets	Annual Grasses: Annual Blue Grass, Annual Rye Grass (Italian Rye Grass), Barnyard Grass (Water Grass), Crab Grass, Foxtails (Green and Yellow), Goose Grass, Volunteer Grains (Barley, Oats and Wheat), Wild Oats, Witch Grass, Fall Panicum Annual Broadleaf Weeds: Common Chickweed, Corn Spurry, Hairy Nightshade[a], Henbit (Deadnettle), Lamb's Quarters, Pigweed (Prostrate, Redroot and Tumble), Purslane, Nettleleaf Goosefoot Perennial Weeds: Quack Grass (Couch Grass and Twitch Grass), Yellow Nutsedge Note: Nettleleaf Goosefoot is not registered for Field Corn	Commercial	Emulsifiable concentrate	Ground sprayer, chemigation	Emulsifiable concentrate formulation can also be sprayed on granular fertilizer that is going to be applied with a ground spreader.
Turnips (rutabagas)		Commercial	Emulsifiable concentrate, granule	Ground sprayer, ground spreader	
Corn (field)		Commercial	Emulsifiable concentrate, granule	Ground sprayer, ground spreader	
Use-Site Category 7, Industrial Oilseed Crops and Fibre Crops; Use-Site Category 13, Terrestrial Feed Crops; Use-Site Category 14, Terrestrial Food Crops					
Flax	Annual Grasses: Annual Blue Grass, Annual Rye Grass (Italian Rye Grass), Barnyard Grass (Water Grass), Crab Grass, Foxtails (Green and Yellow), Goose Grass, Volunteer Grains (Barley, Oats and Wheat), Wild Oats, Witch Grass, Fall Panicum Annual Broadleaf Weeds: Common Chickweed, Corn Spurry, Hairy Nightshade[a], Henbit (Deadnettle), Lamb's Quarters, Pigweed (Prostrate, Redroot and Tumble), Purslane, Nettleleaf Goosefoot Perennial Weeds: Quack Grass (Couch Grass and Twitch Grass), Yellow Nutsedge	Commercial	Emulsifiable concentrate, granule	Ground sprayer, ground spreader	
Sunflower		Commercial	Emulsifiable concentrate, granule	Ground sprayer, ground spreader	

Site(s)	Pests(s)	Marketing Class	Formulation Type	Application Methods and Equipment	Comments
Use-Site Category 27, Ornamentals Outdoor					
Asters, Balsam, Begonia, Dahlia, Daylilies, Marigold, Pansy, Petunia, Zinnia, Pachysandras, Ivy Camellia, Dogwood, Euonymus, Fir, Holly (American and Japanese), Juniper, Leucothoe, Pine, Spruce, Yew (*Taxus*), Rose	Annual Grasses: Annual Blue Grass, Barnyard Grass (Water Grass), Crab Grass, Foxtails (Green, Yellow, Giant), Goose Grass, Johnson Grass Seedlings, Love Grass (Stink Grass), Field Sandbur Annual Broadleaf Weeds: Common Chickweed, Deadnettle (Henbit), Hairy Nightshade, Lamb's Quarters (common), Nettleleaf Goosefoot, Purslane (common), Pigweed (Redroot, Prostrate and Tumble) Perennial Weeds: Nutsedge (Yellow and Purple, Nut Grass), Quack Grass (Couch Grass, Witch Grass)	Domestic	Granule	Home lawn spreader	

[a] Western Canada only.

All uses are supported by the registrant.

Appendix III Toxicology Endpoints for Health Risk Assessment for EPTC

Exposure Scenario	Dose (mg/kg bw/day)	Endpoint	Study	UF/SF or MOE
Acute dietary	LOAEL = 200	Neuronal cell necrosis in the brain of male rats	Acute neurotoxicity—rat	1000 (3-fold LOAEL; 3-fold severity)
	ARfD = 0.2 mg/kg bw			
Chronic dietary	NOAEL = 2.5	Increased cardio-myopathy	2-generation reproduction study—rat	300 (3-fold severity)
	ADI = 0.008 mg/kg bw/day			
Short-term[a] dermal[b]	Oral NOAEL = 22	Total litter loss, decreased maternal body weight gain, reduced food consumption	Developmental neurotoxicity study—rat	300 (3-fold severity at maternal toxicity)
Short-term[a] inhalation	Inhalation NOAEL = 11.3	Myocardial degeneration and hepatocellular lipidosis (fatty degeneration) after 3 weeks	Subchronic inhalation study— rat	300 (3-fold severity)
Aggregate (oral and dermal, 1–7 days)	Oral LOAEL = 200	Neuronal cell necrosis in the brain of male rats	Acute neurotoxicity study—rat	1000 (3-fold LOAEL; 3-fold severity)

[a] Duration of exposure is 1– 30 days

[b] As an oral NOAEL was selected, a dermal absorption factor of 8% should be used in route-to-route extrapolation.

Appendix IV Occupational Risk Estimates for EPTC

Table 1 Mixer/Loader/Applicator Short-Term Farmer Application Exposure and Risk Assessments for EPTC

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[c,d]
						Unit Exposure (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[b]	
Baseline PPE: Open M/L/A wearing a long-sleeved shirt, pants, chemical-resistant gloves											
Emulsifiable concentrate	Groundboom	Alfalfa and birdsfoot	3.4	100	440	51.1	32.5	83.6	525.67	42.05	677
Emulsifiable concentrate	Groundboom	Beans (snap common or dry common including red kidney)	4.4	100	440	51.1	32.5	83.6	525.67	42.05	523
Emulsifiable concentrate	Groundboom	Cicermilk vetch and sweet clover (for seed production)	3.4	100	340	51.14	32.49	83.63	406.20	32.50	677
Emulsifiable concentrate	Groundboom	Corn [annual grasses]	4.4	100	440	51.14	32.49	83.63	525.67	42.05	523
Emulsifiable concentrate	Groundboom	Corn [annual broadleaf weeds]	4.4	100	440	51.14	32.49	83.63	525.67	42.05	523
Emulsifiable concentrate	Groundboom	Corn [perennial weeds]	6.8	100	680	51.14	32.49	83.63	812.41	64.99	339
Emulsifiable concentrate	Groundboom	Flax (spring treatment)	3.4	100	340	51.14	32.49	83.63	406.20	32.50	677
Emulsifiable concentrate	Groundboom	Flax (fall treatment)	4.4	100	440	51.14	32.49	83.63	525.67	42.05	523
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting)	6.8	100	680	51.14	32.49	83.63	812.41	64.99	339

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[c,d]
						Unit Exposure[a] (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily[c]	Abs[d]	
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting), tank mix	4.4	100	440	51.14	32.49	83.63	525.67	42.05	523
Emulsifiable concentrate	Groundboom	Potatoes (Irish, drag-off [come-up, weeding time])	6.8	100	680	51.1	32.5	83.6	812.41	64.99	339
Emulsifiable concentrate	Groundboom	Potatoes (Irish, post-emergence)	4.4	100	440	51.1	32.5	83.6	525.67	42.05	523
Emulsifiable concentrate	Groundboom	Potatoes (Irish, fall treatment)	6.8	100	680	51.14	32.49	83.63	812.41	64.99	339
Emulsifiable concentrate	Groundboom	Sugar beets (fall treatments)	4.4	100	440	51.14	32.49	83.63	525.67	42.05	523
Emulsifiable concentrate	Groundboom	Sunflower (spring treatment)	3.4	100	340	51.1	32.5	83.6	406.2	32.50	677
Emulsifiable concentrate	Groundboom	Sunflower (fall treatment)	4.4	100	440	51.14	32.49	83.63	525.67	42.05	523
Emulsifiable concentrate	Groundboom	Turnips (rutabagas)	3.4	100	340	51.14	32.49	83.63	406.20	32.50	677
Emulsifiable concentrate	Chemigation[e]	Potato (Irish)	4.4	140	616	51.14	N/A	51.14	450.03	36.00	611
Emulsifiable concentrate	Chemigation[e]	Sugar beets	3.4	140	476	51.14	N/A	51.14	347.75	27.82	791
Granular	Solid broadcast spreader	Alfalfa and birdsfoot	3.4	80	272	13.04	15.89	28.93	112.41	8.99	2446
Granular	Solid broadcast spreader	Beans (snap or dry, including red kidney beans)	4.5	80	360	13.04	15.89	28.93	148.78	11.90	1848

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[c,d]
						Unit Exposure (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[a]	
Granular	Solid broadcast spreader	Corn (field, silage, sweet) [annual grasses]	4.4	80	352	13.04	15.89	28.93	145.48	11.64	1890
Granular	Solid broadcast spreader—band	Corn (field, silage, sweet) [annual grasses]	4.40	80	352	13.04	15.89	28.93	145.48	11.64	1890
Granular	Solid broadcast spreader	Corn (field, silage, sweet) [quack grass and yellow nutsedge]	6.80	80	544	13.04	15.89	28.93	224.83	17.99	1223
Granular	Solid broadcast spreader	Flax (spring treatment)	3.40	80	272	13	15.9	28.9	112.41	8.99	2446
Granular	Solid broadcast spreader	Flax (fall treatment)	4.50	80	360	13.04	15.89	28.93	148.78	11.90	1848
Granular	Solid broadcast spreader	Potatoes (Irish, before planting)	6.75	80	540	13.04	15.89	28.93	223.17	17.85	1232
Granular	Solid broadcast spreader	Potatoes (Irish, drag-off [come-up, weeding time])	6.75	80	540	13.04	15.89	28.93	223.17	17.85	1232
Granular	Solid broadcast spreader	Potatoes (Irish, post-emergence)	4.50	80	360	13.04	15.89	28.93	148.78	11.90	1848
Granular	Solid broadcast spreader	Sunflower	3.4	80	272	13	15.9	28.9	112.41	8.99	2446
Granular	Solid broadcast spreader	Sunflower (fall treatment)	4.50	80	360	13.04	15.89	28.93	148.78	11.90	1848

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[c,d]
						Unit Exposure (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[a]	
Granular	Solid broadcast spreader	Turnips (rutabagas)	3.40	80	272	13.04	15.89	28.93	112.41	8.99	2446

ATPD = area treated per day

[a] Absd = Absorbed. Where dermal exposure µg/kg/day = [unit exposure × volume handled × use rate (g/L) × 8% dermal absorption] / 70 kg bw

[b] Where exposure µg/kg/day = [unit exposure × volume handled × use rate (g/L)] / 70 kg bw.

[c] Dermal MOE is based on an oral NOAEL of 22 mg/kg bw/day; target is 300. Inhalation MOE is based on an inhalation NOAEL of 11.3 mg/kg bw/day; target is 300 for inhalation.

[d] Quantitative inhalation assessment was not conducted as it not appropriate to use the PHED for highly volatile chemicals such as EPTC.

[e] There is no applicator exposure because application is done through irrigation system.

Table 2 Mixer/Loader/Applicator Short-Term Custom Applicator Exposure and Risk Assessments for EPTC

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal[1]					Margins of Exposure[2]
						Unit Exposure (µg/kg a.i.)			Exposure[3] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[4]	
Baseline PPE: Open M/L/A wearing a long-sleeved shirt, pants, chemical-resistant gloves											
Emulsifiable concentrate	Groundboom	Alfalfa and birdsfoot	3.4	300	1020	51.1	32.5	83.6	1218.61	97.49	[illegible]
Emulsifiable concentrate	Groundboom	Beans (snap common or dry common including red kidney)	4.4	300	1320	51.1	32.5	83.6	1577.02	126.16	[illegible]
Emulsifiable concentrate	Groundboom	Cicermilk vetch and sweet clover (for seed production)	3.4	300	1020	51.1	32.5	83.6	1218.61	97.49	[illegible]
Emulsifiable concentrate	Groundboom	Corn [annual grasses]	4.4	140	616	51.1	32.49	83.6	735.94	58.88	[illegible]
Emulsifiable concentrate	Groundboom	Corn [annual broadleaf weeds]	4.4	140	616	51.14	32.49	83.63	735.94	58.88	[illegible]
Emulsifiable concentrate	Groundboom	Corn [perennial weeds]	6.8	140	952	51.14	32.49	83.63	1137.37	90.99	[illegible]
Emulsifiable concentrate	Groundboom	Flax (spring treatment)	3.4	300	1020	51.14	32.49	83.63	1218.61	97.49	[illegible]
Emulsifiable concentrate	Groundboom	Flax (fall treatment)	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	[illegible]
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting)	6.8	300	2040	51.14	32.49	83.63	2437.22	194.98	[illegible]
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting), tank mix	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	[illegible]
Emulsifiable concentrate	Groundboom	Potatoes (Irish, drag-off [come-up, weeding time])	6.8	300	2040	51.14	32.49	83.63	2437.22	194.98	[illegible]
Emulsifiable concentrate	Groundboom	Potatoes (Irish, postemergence)	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	[illegible]
Emulsifiable concentrate	Groundboom	Potatoes (Irish, fall treatment)	6.8	300	2040	51.14	32.49	83.63	2437.22	194.98	[illegible]
Emulsifiable concentrate	Groundboom	Sugar beets (fall treatments)	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	[illegible]
Emulsifiable concentrate	Groundboom	Sunflower (spring treatment)	3.4	300	1020	51.14	32.49	83.63	1218.61	97.49	[illegible]
Emulsifiable concentrate	Groundboom	Sunflower (fall treatment)	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	[illegible]

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[c,d]
						Unit Exposure (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[a]	
Granular	Solid broadcast spreader	Turnips (rutabagas)	3.40	80	272	13.04	15.89	28.93	112.41	8.99	2446

ATPD = area treated per day

[a] Absd = Absorbed. Where dermal exposure µg/kg/day = [unit exposure × volume handled × use rate (g/L) × 8% dermal absorption] / 70 kg bw

[b] Where exposure µg/kg/day = [unit exposure × volume handled × use rate (g/L)] / 70 kg bw.

[c] Dermal MOE is based on an oral NOAEL of 22 mg/kg bw/day; target is 300. Inhalation MOE is based on an inhalation NOAEL of 11.3 mg/kg bw/day; target is 300 for inhalation.

[d] Quantitative inhalation assessment was not conducted as it not appropriate to use the PHED for highly volatile chemicals such as EPTC.

[e] There is no applicator exposure because application is done through irrigation system.

Table 2 Mixer/Loader/Applicator Short-Term Custom Applicator Exposure and Risk Assessments for EPTC

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[c]
						Unit Exposure (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[a]	
Baseline PPE: Open M/L/A wearing a long-sleeved shirt, pants, chemical-resistant gloves											
Emulsifiable concentrate	Groundboom	Alfalfa and birdsfoot	3.4	300	1020	51.1	32.5	83.6	1218.61	97.49	226
Emulsifiable concentrate	Groundboom	Beans (snap common or dry common including red kidney)	4.4	300	1320	51.1	32.5	83.6	1577.02	126.16	174
Emulsifiable concentrate	Groundboom	Cicermilk vetch and sweet clover (for seed production)	3.4	300	1020	51.1	32.5	83.6	1218.61	97.49	226
Emulsifiable concentrate	Groundboom	Corn [annual grasses]	4.4	140	616	51.1	32.49	83.6	735.94	58.88	370
Emulsifiable concentrate	Groundboom	Corn [annual broadleaf weeds]	4.4	140	616	51.14	32.49	83.63	735.94	58.88	370
Emulsifiable concentrate	Groundboom	Corn [perennial weeds]	6.8	140	952	51.14	32.49	83.63	1137.37	90.99	240
Emulsifiable concentrate	Groundboom	Flax (spring treatment)	3.4	300	1020	51.14	32.49	83.63	1218.61	97.49	226
Emulsifiable concentrate	Groundboom	Flax (fall treatment)	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	174
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting)	6.8	300	2040	51.14	32.49	83.63	2437.22	194.98	113
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting), tank mix	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	174
Emulsifiable concentrate	Groundboom	Potatoes (Irish, drag-off [come-up, weeding time])	6.8	300	2040	51.14	32.49	83.63	2437.22	194.98	113
Emulsifiable concentrate	Groundboom	Potatoes (Irish, postemergence)	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	174
Emulsifiable concentrate	Groundboom	Potatoes (Irish, fall treatment)	6.8	300	2040	51.14	32.49	83.63	2437.22	194.98	113
Emulsifiable concentrate	Groundboom	Sugar beets (fall treatments)	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	174
Emulsifiable concentrate	Groundboom	Sunflower (spring treatment)	3.4	300	1020	51.14	32.49	83.63	1218.61	97.49	226
Emulsifiable concentrate	Groundboom	Sunflower (fall treatment)	4.4	300	1320	51.14	32.49	83.63	1577.02	126.16	174

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[a]
						Unit Exposure (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[c]	
Emulsifiable concentrate	Groundboom	Turnips (rutabagas)	3.4	300	1020	51.14	32.49	83.63	1218.61	97.49	226
Granular	Solid broadcast spreader	Alfalfa and birdsfoot	3.4	300	1020	13	15.9	28.9	421.55	33.72	652
Granular	Solid broadcast spreader	Beans (snap or dry, including red kidney beans)	4.5	300	1350	13.04	15.89	28.93	557.94	44.63	493
Granular	Solid broadcast spreader	Corn (field, silage, sweet) [annual grasses]	4.4	300	1320	13.04	15.89	28.93	545.54	43.64	504
Granular	Solid broadcast spreader—band	Corn (field, silage, sweet) [annual grasses]	4.4	300	1320	13.04	15.89	28.93	545.54	43.64	504
Granular	Solid broadcast spreader	Corn (field, silage, sweet) [quack grass and yellow nutsedge]	6.8	300	2040	13.04	15.89	28.93	843.10	67.45	326
Granular	Solid broadcast spreader	Flax (spring treatment)	3.4	300	1020	13.04	15.89	28.93	421.55	33.72	652
Granular	Solid broadcast spreader	Flax (fall treatment)	4.5	300	1350	13.04	15.89	28.9	557.94	44.63	493
Granular	Solid broadcast spreader	Potatoes (Irish, before planting)	6.75	300	2025	13.04	15.89	28.93	836.90	66.95	329
Granular	Solid broadcast spreader	Potatoes (Irish, drag-off [come-up, weeding time])	6.75	300	2025	13.04	15.89	28.93	836.90	66.95	329
Granular	Solid broadcast spreader	Potatoes (Irish, postemergence)	4.5	300	1350	13.04	15.89	28.93	557.94	44.63	493
Granular	Solid broadcast spreader	Sunflower	3.4	300	1020	13.04	15.89	28.93	421.55	33.72	652
Granular	Solid broadcast spreader	Sunflower (fall treatment)	4.5	300	1350	13.04	15.89	28.93	557.94	44.63	493
Granular	Solid broadcast spreader	Turnips (rutabagas)	3.4	300	1020	13.04	15.89	28.93	421.55	33.72	652
Medium PPE: Closed M/L, open cab, wearing coveralls over a single layer, chemical-resistant gloves											
Emulsifiable concentrate	Groundboom	Alfalfa and birdsfoot	3.4	300	1020	18.95	21	40	582.71	46.62	472

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[a]
						Unit Exposure (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[a]	
Emulsifiable concentrate	Groundboom	Beans (snap common or dry common including red kidney)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Cicermilk vetch and sweet clover (for seed production)	3.4	300	1020	18.95	21.04	39.99	582.71	46.62	472
Emulsifiable concentrate	Groundboom	Corn [annual grasses]	4.4	140	616	18.95	21.04	40	735.94	58.88	781
Emulsifiable concentrate	Groundboom	Corn [annual broadleaf weeds]	4.4	140	616	18.95	21.04	39.99	735.94	58.88	781
Emulsifiable concentrate	Groundboom	Corn [perennial weeds]	6.8	140	952	18.95	21.04	39.99	1137.37	90.99	506
Emulsifiable concentrate	Groundboom	Flax (spring treatment)	3.4	300	1020	18.95	21.04	39.99	582.71	46.62	472
Emulsifiable concentrate	Groundboom	Flax (fall treatment)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting)	6.8	300	2040	18.95	21.04	39.99	1165.42	93.23	[illegible]
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting), tank mix	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Potatoes (Irish, drag-off [come-up, weeding time])	6.8	300	2040	18.95	21.04	39.99	1165.42	93.23	[illegible]
Emulsifiable concentrate	Groundboom	Potatoes (Irish, postemergence)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Potatoes (Irish, fall treatment)	6.8	300	2040	18.95	21.04	39.99	1165.42	93.23	[illegible]
Emulsifiable concentrate	Groundboom	Sugar beets (fall treatments)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Sunflower (spring treatment)	3.4	300	1020	18.95	21.04	39.99	582.71	46.62	472
Emulsifiable concentrate	Groundboom	Sunflower (fall treatment)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Turnips (rutabagas)	3.4	300	1020	18.95	21.04	39.99	582.71	46.62	472

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[cd]
						Unit Exposure (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[a]	
Emulsifiable concentrate	Groundboom	Turnips (rutabagas)	3.4	300	1020	51.14	32.49	83.63	1218.61	97.49	226
Granular	Solid broadcast spreader	Alfalfa and birdsfoot	3.4	300	1020	13	15.9	28.9	421.55	33.72	652
Granular	Solid broadcast spreader	Beans (snap or dry, including red kidney beans)	4.5	300	1350	13.04	15.89	28.93	557.94	44.63	493
Granular	Solid broadcast spreader	Corn (field, silage, sweet) [annual grasses]	4.4	300	1320	13.04	15.89	28.93	545.54	43.64	504
Granular	Solid broadcast spreader—band	Corn (field, silage, sweet) [annual grasses]	4.4	300	1320	13.04	15.89	28.93	545.54	43.64	504
Granular	Solid broadcast spreader	Corn (field, silage, sweet) [quack grass and yellow nutsedge]	6.8	300	2040	13.04	15.89	28.93	843.10	67.45	326
Granular	Solid broadcast spreader	Flax (spring treatment)	3.4	300	1020	13.04	15.89	28.93	421.55	33.72	652
Granular	Solid broadcast spreader	Flax (fall treatment)	4.5	300	1350	13.04	15.89	28.9	557.94	44.63	493
Granular	Solid broadcast spreader	Potatoes (Irish, before planting)	6.75	300	2025	13.04	15.89	28.93	836.90	66.95	329
Granular	Solid broadcast spreader	Potatoes (Irish, drag-off [come-up, weeding time])	6.75	300	2025	13.04	15.89	28.93	836.90	66.95	329
Granular	Solid broadcast spreader	Potatoes (Irish, postemergence)	4.5	300	1350	13.04	15.89	28.93	557.94	44.63	493
Granular	Solid broadcast spreader	Sunflower	3.4	300	1020	13.04	15.89	28.93	421.55	33.72	652
Granular	Solid broadcast spreader	Sunflower (fall treatment)	4.5	300	1350	13.04	15.89	28.93	557.94	44.63	493
Granular	Solid broadcast spreader	Turnips (rutabagas)	3.4	300	1020	13.04	15.89	28.93	421.55	33.72	652
Medium PPE: Closed M/L, open cab, wearing coveralls over a single layer, chemical-resistant gloves											
Emulsifiable concentrate	Groundboom	Alfalfa and birdsfoot	3.4	300	1020	18.95	21	40	582.71	46.62	472

Formulation	Application Equipment	Crop [pest]	Application Rate (kg a.i./ha)	ATPD (ha)	a.i. handled/ day (kg)	Dermal					Margins of Exposure[c]
						Unit Exposure (µg/kg a.i.)			Exposure[b] (µg/kg/day)		Dermal
						M/L	App	Total	Daily	Absd[a]	
Emulsifiable concentrate	Groundboom	Beans (snap common or dry common including red kidney)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Cicermilk vetch and sweet clover (for seed production)	3.4	300	1020	18.95	21.04	39.99	582.71	46.62	472
Emulsifiable concentrate	Groundboom	Corn [annual grasses]	4.4	140	616	18.95	21.04	40	735.94	58.88	781
Emulsifiable concentrate	Groundboom	Corn [annual broadleaf weeds]	4.4	140	616	18.95	21.04	39.99	735.94	58.88	781
Emulsifiable concentrate	Groundboom	Corn [perennial weeds]	6.8	140	952	18.95	21.04	39.99	1137.37	90.99	506
Emulsifiable concentrate	Groundboom	Flax (spring treatment)	3.4	300	1020	18.95	21.04	39.99	582.71	46.62	472
Emulsifiable concentrate	Groundboom	Flax (fall treatment)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting)	6.8	300	2040	18.95	21.04	39.99	1165.42	93.23	236
Emulsifiable concentrate	Groundboom	Potatoes (Irish, before planting), tank mix	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Potatoes (Irish, drag-off [come-up, weeding time])	6.8	300	2040	18.95	21.04	39.99	1165.42	93.23	236
Emulsifiable concentrate	Groundboom	Potatoes (Irish, postemergence)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Potatoes (Irish, fall treatment)	6.8	300	2040	18.95	21.04	39.99	1165.42	93.23	236
Emulsifiable concentrate	Groundboom	Sugar beets (fall treatments)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Sunflower (spring treatment)	3.4	300	1020	18.95	21.04	39.99	582.71	46.62	472
Emulsifiable concentrate	Groundboom	Sunflower (fall treatment)	4.4	300	1320	18.95	21.04	39.99	754.10	60.33	365
Emulsifiable concentrate	Groundboom	Turnips (rutabagas)	3.4	300	1020	18.95	21.04	39.99	582.71	46.62	472

Table 3 Mixer/Loader/Applicator Impregnated Dry Fertilizer Scenarios Short-Term Exposure for EPTC

Application Equipment	Crop	Formulation	Maximum Rate (kg a.i./ha)	ATPD (ha/day)	Dermal MOE (Target:300)[e]			
					Baseline PPE[a]	Medium PPE[b]	Maximum PPE[c]	Engineering Controls[d]
Farmer: Mixing/Loading/Applying Fertilizer Impregnated with EPTC								
Mixing/ Loading: PHED[g] Applying: with broadcast spreader	Corn, potatoes	Emulsifiable concentrate	6.8	80	530	920	1100	980
	Flax, beans, sugar beets, sunflower		4.5	80	800	1400	1600	1500
	Alfalfa, birdsfoot, vetch, clover, turnips		3.4	80	1100	1800	2100	2000
Mixing/ Loading: Fenske[h] Applying: with broadcast spreader	Corn, potatoes	Emulsifiable concentrate	6.8	65	2	5	8	5
	Flax, beans, sugar beets, sunflower		4.5	65	3	8	12	8
	Alfalfa, birdsfoot, vetch, clover, turnips		3.4	65	4	11	16	11
Custom Mixing/Loading: Mixing/Loading Fertilizer Impregnated with EPTC in a Commercial Facility								
M/L: PHED[i]	Corn, potatoes	Emulsifiable concentrate	15 422[j]		N/A	N/A	N/A	130
	Flax, beans, sugar beets, sunflower		10 206[k]					200
	Alfalfa, birdsfoot, vetch, clover, turnips		7711[l]					260

Application Equipment	Crop	Formulation	Maximum Rate (kg a.i./ha)	ATPD (ha/day)	Dermal MOE (Target:300)[e]			
					Baseline PPE[a]	Medium PPE[b]	Maximum PPE[c]	Engineering Controls[d]
Custom Applying: Applying of Fertilizer Impregnated with EPTC from a Commercial Facility								
App: with broadcast spreader	Corn, potatoes	Granular	6.8	140	1300	N/A	N/A	N/A
	Flax, beans, sugar beets, sunflower		4.5	140	1900			
	Alfalfa, birdsfoot, vetch, clover, turnips		3.4	140	2500			

Shaded cells indicate MOEs that are less than target.

a Baseline PPE: Open M/L, open cab, long-sleeved shirt, pants, chemical-resistant gloves

b Medium PPE: Open M/L, open cab, coveralls over long pants, chemical-resistant gloves

c Maximum PPE: Open M/L/, open cab, chemical-resistant coveralls, chemical-resistant gloves

d Engineering Controls — Farmer: Open M/L wearing coveralls over long-sleeved shirt, pants, chemical-resistant gloves closed cab wearing long-sleeved shirt, long pants
— Custom: Closed M/L, wearing coveralls over long-sleeved shirt, long pants, chemical-resistant gloves

e Dermal MOEs based on an oral NOAEL 22 mg/kg bw/day with a target MOE of 300

f Quantitative inhalation assessment was not conducted as it not appropriate to use the PHED for highly volatile chemicals, such as EPTC

g PHED data was used to estimate exposure from mixing/loading/application of solid fertilizer impregnated with EPTC. Open M/L/A using a broadcast spreader. Exposure is expected to be underestimated.

h Data from the Fenske study (1990) was used to estimate exposure from mixing/loading/application of solid fertilizer impregnated with EPTC.

i Closed M/L scenario from the PHED. Considered to be an underestimate of exposure.

j Amount handled per day was a product of multiplying the 453 592 kg of fertilizer a commercial facility could handle per day by the maximum rate of pesticide (6.8 kg a.i./ha), divided by the minimum rate of fertilizer (200 kg/ha), as listed on the label.

k Amount handled per day was a product of multiplying the 453 592 kg of fertilizer a commercial facility could handle per day by the maximum rate of pesticide (4.5 kg a.i./ha), divided by the minimum rate of fertilizer (200 kg/ha), as listed on the label.

l Amount handled per day was a product of multiplying the 453 592 kg of fertilizer a commercial facility could handle per day by the maximum rate of pesticide (3.4 kg a.i./ha), divided by the minimum rate of fertilizer (200 kg/ha), as listed on the label.

Table 4 Restricted-Entry Intervals for Commercial Postapplication Activities

Activity	Crop Height/ Foliage Development	Transfer Coefficient (cm^2/hr)	Rate (kg a.i./ha)	Safe Residue Limit [c]	MOE[a] (Day 0)	REI[b, c, d] (days)
Workers in Potato Fields				**Target: 300**		
Irrigation, scouting	Low/Full	1500	4.4	14.6	185	0
Hand weeding	Low/All	300		72.9	240	0
Irrigation, scouting	Low/Minimum	300		72.9	910	0
Mechanical harvesting, weeding	Low/Full	None				

Shaded cells indicate MOEs that are less than target.

a Based on worker short-term oral NOAEL of 22 mg/k bwg/day and target MOE of 300.

b REI = restricted-entry interval

c The REI is the length of time that it takes for the dissipation to reach the safe residue limit (SRL), which is calculated using the following equation:

$$\text{SRL } (\mu g/cm^2) = \frac{\text{NOAEL } (\mu g/kg) \times \text{bw (kg)}}{\text{TC } (cm^2/hr) \times \text{exposure time (hrs)} \times \text{safety factor (unitless)} \times \text{dermal absorption (8\%)}}$$

d As no DFR studies were submitted, a peak default DFR value of 20% of the application rate was used. This is considered to be an overestimate of postapplication exposure because EPTC is highly volatile and so much of the residue would have volatilized.

Appendix V Residential Risk Estimates for EPTC

Table 1 Adult and Youth Short-Term Applicator Exposure and Risk Assessment on Residential Gardens and Ornamentals

Application Equipment[a]	Data Source[b]	Rate (g a.i./m²)	Area Treated[c] per Day (m²/day)	Dermal Unit Exposure (µg/kg handled)	Dermal Dose[d] µg/kg/day	Dermal MOE[e,f] (Target = 1000)
Annual Weed Control						
Push rotary spreader	ORETF	0.575	1000	1378	0.91	24 000
Belly grinder[g]	PHED	0.575	100	252837.88	16.62	1320
Granules dispersed by hand[g]	PHED	0.575	100	172895.98	11.36	1940
Quack Grass and Nut Grass Control						
Push rotary spreader	ORETF	0.69	1000	1378	1.09	20000
Belly grinder[g]	PHED	0.69	100	252837.88	19.9	1100
Granules dispersed by hand[g]	PHED	0.69	100	172895.98	13.6	1600

Shaded cells indicate MOEs that are less than target.

a Homeowner PPE consists of a short-sleeved shirt, shorts, and no gloves.

b Median unit exposures are from ORETF; Best-fit unit exposures are from the PHED.

c From *Recommended Revisions to the Standard Operating Procedures (SOP's) for Residential Exposure Assessments* (USEPA 2001): 100 m² for belly grinders and bait by hand to gardens, 1000 m² for push rotary spreads based on 10,000 ft² (1/4 acre, larger garden in a farm-type setting).

d Where dermal dose µg/kg/day = [unit exposure × area treated/day × use rate (g/m²) × 8% dermal absorption] / 70 kg bw

e Based on an oral NOAEL of 22 mg/kg bw/day; target is 300.

f Quantitative inhalation assessment was not conducted as it not appropriate to use the PHED for highly volatile chemicals such as EPTC.

g No data were available for "no glove" scenarios in the PHED, so gloved scenarios were used as surrogate. These are considered to underestimate the exposure to homeowners because homeowners are considered to not wear gloves.

Table 2 Adult and Youth Postapplication Exposure and Risk Assessments on Residential Gardens and Ornamentals

Scenario	Air Concentration[a] (mg/m^3)		Inhalation Rate[b] (m^3/hr)	Inhalation Exposure[c] (µg/kg bw/day)	Inhalation MOE[d]
Granular Formulation					**Target : 300**
Adult (70 kg)	0–2 hours	67	1	641	18
	2–4 hours	21		201	56
	4–6 hours	3.1		29.6	380
Youth (39 kg)	0–2 hours	67	1	1151	10
	2–4 hours	21		360	31
	4–6 hours	3.1		53.3	212

Shaded cells indicate MOEs that are less than target.

a Air concentrations were taken from the soil volatility study and normalized to the residential used rate.

b Taken from *Recommended Revisions to the Standard Operating Procedures (SOP's) for Residential Exposure Assessments* (USEPA 2001).

c Inhalation exposure = (concentration in air × inhalation rate × exposure time) / bw. Exposure time is 0.67 hours for adult and youth.

d Adult and youth inhalation MOE is based on an inhalation NOAEL of 11.3 mg/kg bw/day, with a target of 300.

Appendix VI Summary of Label Amendments for Commercial Class Products Containing EPTC

(**Note:** The information presented below does not identify all label requirements for individual end use products such as first aid statements, disposal statements, precautionary statements and supplementary PPE that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in summary.)

COMMON NAME: EPTC

CHEMICAL NAME: *S*-ethyl dipropylthiocarbamate

FORMULATION TYPE: Emulsifiable Concentrate or Emulsion, Granular, Solution

USE-SITE CATEGORY: Use-Site Category #7 Industrial Oilseed Crops and Fibre Crops
Use-Site Category #13 Terrestrial Feed Crops
Use-Site Category # 14 Terrestrial Food Crops
Use-Site Category #27 Ornamentals Outdoor

PERSONAL PROTECTIVE EQUIPMENT:

Label Statements for Commercial Class Granular Products
For the granular formulation, the following personal protective equipment is required for mixers, loaders and applicators:

> Wear long-sleeved shirt and long pants, chemical-resistant gloves, socks, chemical-resistant footwear and respirator during mixing, loading, application, clean up and repair. The respirator must be equipped with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister approved for pesticides.

Label Statements For Commercial Class Emulsifiable Concentrate Products
For the emulsifiable concentrate formulation, the following personal protective equipment is required for mixers, loaders and applicators:

> Wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, socks, chemical-resistant footwear and respirator during mixing, loading, application, clean up and repair activities. The respirator must be equipped with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister approved for pesticides.
>
> When handling greater than 755 kilogram of active ingredient per day (i.e. treating over 110 ha at highest label rate of 6.8 kg a.i. ha) a closed mixing and

loading system is required. Handlers must wear coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, socks, chemical-resistant footwear during application, clean up and repair. A respirator is also required during application. The respirator must be equipped with a NIOSH/MSHA/BHSE approved organic-vapour-removing cartridge with a prefilter approved for pesticides OR a NIOSH/MSHA/BHSE approved canister approved for pesticides.

ENVIRONMENTAL HAZARDS:

The following statements must be added to the product label:

TOXIC to wild mammals. **TOXIC** to aquatic organisms and terrestrial plants.

Observe buffer zones specified under **DIRECTIONS FOR USE**.

DIRECTIONS FOR USE:

For clarification, the following statement must be added to the product label:

Make no more than two applications per year.

For end-use product labels with use directions for sugar beet, under "Sugar Beets - Sprinkler irrigation water", remove any references to the tank mix with the product RO-NEET© because this product is no longer registered. Add the following statement to labels:

Do not apply within 49 days of harvest.

The following statements must be added to all product labels:

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural and Biological Engineers (ASABE) medium classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:

Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer, inter-row hooded sprayer, spot treatment, soil drench and soil incorporation.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands), sensitive freshwater habitats (such as

lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:		
		Aquatic Habitat of Depths:		Terrestrial Habitat
		Less than 1 m	Greater than 1 m	
Field sprayer*	Corn, potatoes	1	1	4
	Flax, cicer-milk, sugar beets	0	0	2

*For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

References

Fenske, R.A., A.M. Blacker, S.J. Hamburger and G.S. Simon. 1990. Worker exposure and protective clothing performance during manual seed treatment with lindane. *Archives of Environmental Contamination and Toxicology*. 19:190–196.

USEPA. 1999. *Reregistration Eligibility Decision (RED) EPTC*. United States Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances. Document number EPA 738-R-99-006.

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